

REMARKS

This Preliminary Amendment constitutes the proper Submission with the RCE being concurrently filed and fully complies with M.P.E.P. § 706.07(h)(II).

Also, a Petition for Extension of Time is being concurrently filed with this Preliminary Amendment. Thus, this Preliminary Amendment is being timely filed.

Applicants respectfully request the Examiner to reconsider the present application in view of the foregoing amendments to the claims and the following remarks.

Status of the Claims

Claims 23, 24, 26, 27, 29-32, 34, 35, 38, 39 and 41 are now pending in this application. Claims 23, 31, 39 and 41 are independent.

In the present Amendment, claims 23, 31, 39 and 41 have been amended. Also, claims 25, 28, 33, 36, 37 and 40 have been canceled without prejudice or disclaimer of the subject matter contained therein.

Support for the amendments to claims 23, 31, 39 and 41 can be found in the canceled claims (see also the present specification, such as paragraphs [0028], [0029], [0031] and [0039]). No new matter has been added.

Based upon the above considerations, entry of the present amendment is respectfully requested.

In view of the following remarks, Applicants respectfully request that the Examiner withdraw the only rejection and allow the currently pending claims.

Substance of the Interview

Applicants thank the Examiners for their time, helpfulness and courtesies extended to Applicants' representatives during the Interview of July 8, 2010. The assistance of the Examiners in advancing prosecution of the present application is greatly appreciated. In compliance with M.P.E.P. § 713.04, Applicants submit the following remarks.

The Interview Summary form amply summarizes the discussions at the Interview. Various ways of addressing the prior art rejections were discussed, and suggestions were

discussed that may be drafted to cover particular aspects of the invention as not described by the prior art. Applicants also proposed certain Declarations to address the Examiner's concerns. Those amendments are reflected herein. Also, Applicants are herein attaching two Rule 132 Declarations (explained in more detail below).

Issues under 35 U.S.C. § 103(a)

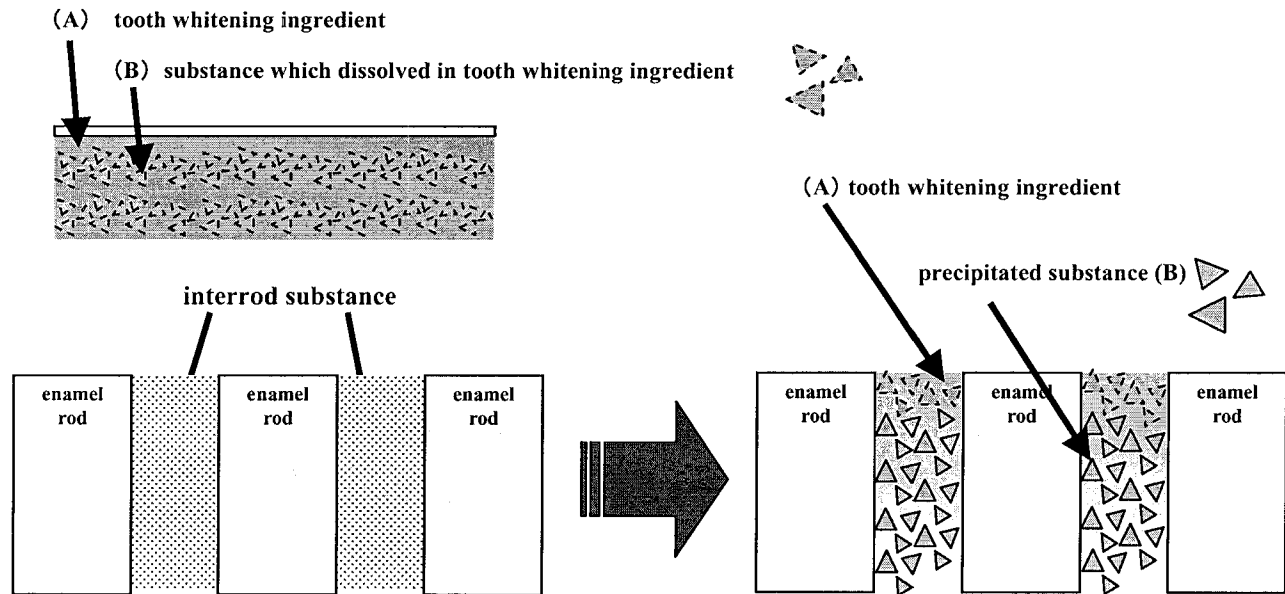
Claims 23-41 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Oniki** (WO 03/030851) in view of **Takeda '652** (U.S. 2001/0007652). This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here. Applicants note that some of the disputed claims have been canceled.

The Present Invention and Its Advantages

An object of the present invention is to provide a tooth whitening set (see independent claims 23, 31 and 41) and a method (see independent claim 39) for reversibly making teeth look white. The present invention achieves such a whitening effect by changing the optical properties of the enamel without using any peroxide. With the present invention, teeth look white while at the same time permits teeth to restore their original color in the presence of water (e.g., from saliva). Also with the present invention, the whitening effect last over a relatively longer period of time.

The present invention is directed to using a nonaqueous gel composition that produces the effect of making the enamel of the tooth apparently look white. The nonaqueous gel composition comprises a combination of ingredients (A) and (B). Ingredient (A) is the tooth whitening ingredient; ingredient (B) dissolves in the tooth whitening ingredient (A). Ingredient (B) is a whitening effect endurance improver (see present specification at paragraph [0019] on page 7). When combined, ingredients (A) and (B)) penetrate into the enamel layer of the tooth (e.g., into the interred space between enamel rods), and then ingredient (B) precipitates therein. Once in place, the precipitated substance (B) does not easily leach out. Applicants note the depiction below:



As a result of using the combination of (A) and (B), the present invention changes the optical properties of the enamel, or put differently gives a superior whitening effect (such as refractive index and reflectance; see, e.g., paragraph [0030] at page 11 of the present specification). Because the present invention does not involve chemical reactions such as that found in methods/whitening sets using hydrogen peroxide, the present invention is safe. Further, the present invention achieves a whitening effect that lasts longer than previously known methods and whitening sets.

With these features and advantages in mind, Applicants respectfully submit that Oniki is improperly combined with Takeda '652 for several reasons.

Distinctions Over Cited Combination and the Improper Combination of Oniki and Takeda '652

The compositions of Oniki and Takeda '652 whiten teeth by using a composition that is different from the present invention and in a different manner.

Applicants note that a nonaqueous gel composition with a water content of less than 3% by weight of the total amount of the composition and being free of a peroxide is being claimed. In this regard, the Takeda '652 dentifrice composition contains significant amounts of water as

an essential component. Specifically, Applicants note all of the working examples of Takeda '652 are more water based. For instance, Examples 1 and 2 (at page 2) contain 31.4% and 28.6% purified water, respectively. The composition of Oniki also contains water as is apparent from the composition examples.

Applicants even note the toothpaste composition of Example 3 of Takeda, which is as follows:

Components	wt. %
Silicic acid anhydride	15.0
Sorbitol (70%)	63.0
Glycerol	3.0
Propylene glycol	8.0
Shellac	2.0
Sodium carboxymethyl cellulose	0.8
Sodium lauryl sulfate	1.5
Flavor	1.3
Sodium saccharin	0.1
Methyl p-hydroxybenzoate	0.1
Sodium benzoate	0.1
Purified water	3.1
Total	100.0

Although the amount of water is 3.1 wt%, sorbitol (70%) contains 30 wt% water. Therefore, 63.0 wt% of sorbitol (70%) contains 18.9 wt% water, and thus the total water content of the toothpaste composition of Example 3 is $3.1 \text{ wt\%} + 18.9 \text{ wt\%} = 22 \text{ wt\%}$.

The toothpaste composition containing a considerable amount of water does not fully give the whitening effect as achieved by the present invention. Applicants even respectfully refer the Examiner to Comparative Example 5 of Table 4 of the present specification. Therefore,

should one of ordinary skill in the art actually combine the disclosures of Takeda '652 and Oniki, this would lead to a composition containing water, and thus does not lead the instantly claimed nonaqueous gel composition which substantially does not contain water.

As evidence of how Takeda '652 and Oniki work, Applicants herein enclose a (first) **Declaration** under 37 C.F.R. § 1.132 that pertains to such conventional methods. Specifically, and as explained in the first Rule 132 Declaration, the Takeda '652 and Oniki compositions/methods involve large amounts of water. As a result, the shellac of Takeda '652 is not properly dissolved, and thus cannot penetrate into the enamel of the teeth. Further, Takeda '652 merely coats the teeth to give a whitening effect. But at the same time, such a coating of Takeda '652 is susceptible to saliva, and the whitening effect does not last for a long time.

And as explained above, the present invention is directed to using a nonaqueous gel composition comprising a combination of ingredients (A) and (B). When these ingredients are combined, especially when in the nonaqueous gel composition, ingredient (B) dissolves, will penetrate into the enamel layer of teeth, and then precipitate thereby staying within the interred space between enamel rods. Thus, the present inventors have found a method that is an improvement over the Oniki method since, for example, the present invention is safer and has a longer lasting whitening effect. Therefore, the inventive tooth whitening set can overcome the problems associated with the Oniki method.

Takeda '652 also discloses the following:

[0018] A process for producing the dentifrice compositions according to the present invention is the same as the production process for the conventional dentifrice compositions except that the wax or shellac is dissolved in a substance commonly used in the conventional dentifrice compositions, such as propylene glycol. FOMBLIN HC (Trade Mark) is insoluble in almost all solvents, but may be mixed for use with, for example, propylene glycol or glycerol because its emulsifiability and dispersibility are good. The disinfectant may also be dissolved or dispersed for use in a solvent generally used in dentifrice compositions.

As explained in the first Rule 132 Declaration, although in Takeda '652 shellac is dissolved in a solvent such as propylene glycol upon preparation of the dentifrice composition to mix it with the other components, shellac is not present in a dissolved state in the resulting dentifrice. Instead, since a considerable amount of water is present in the dentifrice composition, shellac is present as an

undissolved solid or paste in the resulting dentifrice composition. In addition, the solvent capable of dissolving shellac such as propylene glycol is only present in an insufficiently small amount in the dentifrice composition. Thus, the shellac does not infiltrate the enamel of the teeth. Shellac or wax may cover the surface of teeth in a pasty state, which also prevents infiltration of polyols (*i.e.*, the inventive component (A)). The precipitated shellac or wax on the surface of teeth is brittle and easily removed from the surface of teeth. Thus, the whitening effect does not endure for a long time when compared to the present invention.

Further, Applicants respectfully point out that the Takeda '652 composition is applied to teeth as the conventional application method of dentifrice compositions via tooth brushing. In the Takeda '652 composition, the infiltration of polyols into the tooth enamel would not be attained due to dilution of its composition by invasion of saliva into the composition in addition of the considerable amount of water. Takeda '652 fails to disclose and teach the application of the nonaqueous gel composition by using the special tool of the inventive set and method and the feature thereof as instantly claimed. Further, Takeda '652 does not recognize using a nonaqueous gel composition. For instance, the toothpaste of Example 1 or Example 2 in Takeda '652 not only contains high amounts of water, when used the saliva further dilutes its composition. This leads to a lack of infiltration of polyols into the enamel, and would not lead to a composition that attains a whitening effect as achieved by the present invention.

Applicants also note, e.g., paragraph [0039] of Takeda '352 which discusses its composition covering the surfacing of the teeth. Further, a whitening method of the primary reference of Oniki has the problem that the whitening effect does not endure for a long period of time. This disadvantage of Oniki is also mentioned in Applicants' specification in paragraph [0006] at page 2

In this regard, M.P.E.P. § 2143 sets forth the guidelines in determining obviousness. First, the Examiner has to take into account the factual inquiries set forth in *Graham v. John Deere*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), which has provided the controlling framework for an obviousness analysis. The four *Graham* factors are: determining the scope and content of the prior art; ascertaining the differences between the prior art and the claims that are at issue; resolving the level of ordinary skill in the pertinent art; and evaluating any evidence of

secondary considerations (e.g., commercial success; unexpected results). 383 U.S. 1, 17, 148 USPQ 459, 467 (1966). Second, the Examiner has to provide some rationale for determining obviousness, wherein M.P.E.P. § 2143 sets forth some rationales that were set established in the recent decision of *KSR Int'l Co. v Teleflex Inc.*, 550 U.S. 398, 82 USPQ2d 1385 (U.S. 2007).

Here, Applicants respectfully submit that the *Graham* factors weigh in Applicants' favor, and that a proper rationale has not been set forth in forming the outstanding rejection. For instance, when considering the *Graham* factor of ascertaining the differences between the prior art and the claims that are at issue, the cited references use aqueous compositions (e.g., Example 3 of Takeda '652) used in aqueous environments (e.g., toothpaste involving saliva). There is an improper rationale in combining the references since, e.g., the shellac would not properly dissolve.

Applicants note that Oniki is improperly combined with Takeda '652 for another reason. As admitted in the previous Office Action (page 5), the primary reference of Oniki fails to disclose the use of the ingredient (B) of the inventive tooth whitening set/method and the advantages thereof. Thus, Takeda '652 is cited. However, Takeda '652 discloses a dentifrice composition for imparting gloss on teeth comprising shellac or wax, and further comprising propylene glycol and/or glycerin as a solvent. Takeda '652 still fails to disclose the acrylic acid copolymers of the ingredient (B) of the inventive tooth whitening set/method. Therefore, the use of the acrylic acid copolymers as the ingredient (B) of the inventive tooth whitening set/method and the feature thereof are not expected from Takeda '652.

Furthermore, although Takeda '652 discloses the use of shellac, the amount of the polyols is fewer than the amount of the tooth whitening ingredient (A) (50.0 to 99.5 % by weight) of the inventive tooth whitening set/method. This is yet another distinction from the present invention.

Thus, Applicants respectfully submit that Oniki is improperly combined with Takeda '652.

Unexpected Results

A comparative showing need not compare the claimed invention with all of the cited prior art, but only with the closest prior art. *See* M.P.E.P. §§ 716.02(b) and 716.02(e); *see also In re Fenn et al.*, 208 USPQ 470 (CCPA 1981); *In re Holladay*, 199 USPQ 516 (CCPA 1978). Further, U.S. case law states that a patent applicant may compare the claimed invention with prior art that is closer to the invention than the prior art relied upon by the Examiner. *See In re Holladay*, 584 F.2d 384, 199 USPQ 516 (CCPA 1978); *see also* M.P.E.P. § 716.02(e)(I). Finally, Applicants are not required to compare the claimed invention with subject matter that does not exist in the prior art. *See In re Geiger*, 815 F.2d 686, 689, 2 USPQ2d 1276, 1279 (Fed. Cir. 1987); *In re Chapman*, 357 F.2d 418, 148 USPQ 711 (CCPA 1966).

In this regard, Applicants herein enclose a second Rule 132 **Declaration** depicting unexpected results for the present invention. As stated in paragraph 5 of the second Rule 132 Declaration, Applicants have tested embodiments that actually exist, as well as those in the cited references that are closer to the invention than what are actually disclosed therein. For instance, Applicants note “Comparison No. 1 (Takeda)” at page 4 of the Rule 132 Declaration, which is Example 3 in the cited primary reference. Further, “Comparison No. 2 (Oniki)” at page 5 of the Declaration corresponds to Example 5 of Oniki, except the composition is coated on a tape. “Comparison (Oniki)” also at page 5 of the Declaration is closer to the presently claimed invention. For consistency, the application to teeth of the inventive examples and the comparative examples was for 3 minutes.

As stated in the Rule 132 Declaration, the present invention has achieved unexpected and superior results in terms of the whitening effect and the duration thereof. Further, the present invention achieves such a whitening effect by changing the optical properties of the enamel without using any peroxide. With the present invention, teeth look white while at the same time permits teeth to restore their original color in the presence of water (e.g., from saliva).

Finally, Applicants respectfully point out *In re Rinehart*, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976), which states:

When prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over. * * * An earlier decision should not, as it was here, be considered as set in concrete, and applicant's rebuttal evidence

then be evaluated only on its knockdown ability. Analytical fixation on an earlier decision can tend to provide that decision with an undeservedly broadened umbrella effect. **Prima facie obviousness is a legal conclusion, not a fact. Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself.** *
* * [A] final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached by an earlier board upon a different record.

(Emphasis added.) Thus, after a *prima facie* case of obviousness has been made (Applicants are not conceding this point) and rebuttal evidence submitted, all the evidence must be considered anew. Applicants herein make that request, especially in view of both Rule 132 Declarations.

Summary

Oniki is being improperly cited and combined with Takeda '652. Further, the present invention is still not achieved due to the aqueous nature of the reference compositions. In any event, unexpected results exist for the present invention, wherein the present invention achieves a superior, longer lasting and safer whitening effect. It is believed that any concerns of the Examiner have been sufficiently addressed with the two filed Rule 132 Declarations.

Therefore, the present invention is patentably distinct from Oniki and Takeda '652, and one ordinary skill in the art would not combine these references in an effort to achieve the present invention. Reconsideration and withdrawal of this rejection are respectfully requested.

Information Disclosure Statement

Applicants note that an Information Disclosure Statement was filed on June 21, 2010, which is after issuance of the latest Office Action. Consideration of the cited references and a returned, initialed copy of the SB/08 form are respectfully requested.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and

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complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

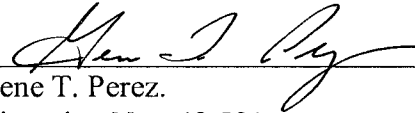
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Eugene T. Perez, Registration No. 48,501, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: August 17, 2010

Respectfully submitted,

By



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Attachments: First Declaration under 37 C.F.R. § 1.132
Second Declaration under 37 C.F.R. § 1.132